

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)
THIS DOCUMENT RELATES TO ALL CASES	

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO
TORRENT'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

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ARGUMENT¹

I. Scierter is Established as a Matter of Law

1. Torrent Acted Knowingly

Contrary to Torrent’s assertions that there was “no evidence” it knew of the potential for nitrosamine contamination in the valsartan API, (*e.g.* Torrent Br., at 5.) the record reflects longstanding knowledge by Torrent that nitrosamines could and did form in the valsartan API. (*e.g.*, Torrent SOMF ¶ 50, 50(a).)

a. Torrent First Learned of the Potential for Nitrosamine Formation Before It Began Selling Valsartan in the United States

Torrent started selling VCDs manufactured with C code valsartan API from ZHP in 2015. (Torrent SOMF ¶ 5.) Torrent began the process of qualifying what it characterized as a [REDACTED]. (Ex. 32; Ex. 34; Ex. 3, at 72:12–24, 74:10–24.) During this process, and before it began selling its VCDs in the United States, Torrent acquired information demonstrating the potential for nitrosamine formation in the valsartan API.

First, Torrent’s corporate representative and head of quality admitted that [REDACTED]

[REDACTED]

[REDACTED]. (Ex. 1, at 334:12–23; Ex. 2, at 449:13–18,

¹ Plaintiffs incorporate by reference Plaintiffs’ Omnibus Motion for Partial Summary Judgment, Plaintiffs’ Motion for Partial Summary Judgment Against Torrent, and Plaintiffs’ Statement of Undisputed Material Facts – Torrent (SOMF). Exhibits referenced herein are Exhibits to the Certification of Daniel Nigh or Supplemental Certification of Daniel Nigh.

468:7–9; Torrent SOMF ¶ 50, 50(a).) The chemistry knowledge needed to perform this analysis was available as early as the 1980s or 1990s, before valsartan was even on the market. [REDACTED] While Torrent did not have access to the entire DMF, (*id.*), it was able to and did view the open part of the DMF [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Torrent’s argument that it was unaware of the potential for nitrosamine formation is disingenuous given that this potential was evident from the start.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Torrent never tested for nitrosamines in its product. (Ex. 1, at 284:3–285:20, 286:7–12.)²

² Nothing stopped Torrent from outsourcing testing of the API or developing a method to test for nitrosamines. (SOMF ¶ 20.) Indeed, the GC-MS and LC-MS method that ultimately identified

Years before ZHP notified Torrent that there were genotoxic impurities in the valsartan API, Torrent had all the information to make that determination on its own. Its own refusal to acknowledge these facts does not insulate it from liability. At a *minimum* it constitutes a reckless disregard for the truth, which is actionable fraud. *See, e.g., Zeman v. Lufthansa German Airlines*, 699 P.2d 1274, 1285 (Alaska 1985).³

b. Torrent Learned More About the Nitrosamine Contamination on June 20, 2018

Though Torrent's corporate representative [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

nitrosamines in valsartan [REDACTED]

³⁵ *See also Muccio v. Hunt*, 490 S.W.3d 310, 312–13 (Ark. 2016) (“insufficient knowledge to make the representation” satisfies knowledge); *Ocean Bank of Miami v. Inv-Uni Inv. Corp.*, 599 S.W. 2d 694, 697 (Fla. App. 1992); *Budget Truck Sales, LLC v. Tilley*, 419 P.3d 1139, 1145 (Idaho 2018) (“ignorance of its truth” satisfies knowledge); *Rosen v. Bd. of Med. Examiners of State of Iowa*, 539 N.W.2d 345, 350 (Iowa 1995); *U.S. Bank N.A. v. Cold Spring Granite Co.*, 802 N.W.2d 363, 373 (Minn. 2011) (“without knowing whether it was true or false” satisfies knowledge); *Libby Hill Seafood Rests., Inc. v. Owens*, 3030 S.E.2d 565, 568 (N.C. Ct. App. 1983); *Siegel v. Ringer*, 94 N.E.3d 1178, 1185 (Ohio 2017); *N. Am. Truck & Trailer, Inc. v. M.C.I. Comm’n Servs., Inc.*, 751 N.W.2d 710, 713 (S.D. 2008).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This flies in the face of Torrent’s own admission that “genotoxic impurity control” is the “most significant factor” for compliance with FDA and ICH regulations and that impurities “should be investigated.” (SOMF ¶ 51, 53.)

Torrent’s attempts to draw parallels between this case and *Harris v. Pfizer, Inc.*, fall flat. In *Harris*, the plaintiffs alleged *Pfizer* should have known of nitrosamine contamination because *its distributor* (not *Pfizer* itself) was warned about the risk. 586 F. Supp. 3d 231, 241 (S.D.N.Y. 2022). [REDACTED]

⁴ Torrent’s corporate behavior demonstrates that Torrent was nonetheless aware that its products were contaminated: Torrent evaluated the financial impact that a recall of its VCDs would have on it, (Ex. 30.), and communicated internally that the FDA would be expecting them to show that the product they had been selling the entire time had no NDMA. (Ex. 31; Ex. 32.) Torrent began drafting a recall notice on July 12, 2018. (Ex. 32; Ex. 35; Ex. 36.)

[REDACTED]

[REDACTED] At this point, Torrent knew—or recklessly disregarded the truth—of nitrosamine formation in its valsartan API purchased from ZHP. *See, e.g., Ocean Bank of Miami v. Inv-Uni Inv. Corp.*, 599 S.W. 2d 694, 697 (Fla. App. 1992). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

c. ZHP Confirmed What Torrent Already Knew on August 3, 2018

Torrent does not dispute that it was aware its VCDs contained nitrosamines by August 3, 2018. (*See* Torrent Br., at 5.)⁵ Rather, it merely argues that there was no evidence of scienter *before* August 3, 2018 and therefore, claims Plaintiffs have no fraud claim *at all*. In fact, the undisputed material facts demonstrate that the elements of fraud—including knowledge—are satisfied before *and after* August 3, 2018. However, Torrent entirely fails to address Plaintiffs’ fraud claims for the period from August 3, 2018 through August 17, 2018 when Torrent continued to knowingly,

⁵ Torrent alleges that it was “unaware” of the nitrosamine contamination prior to August 3, 2018 and only learned of it on that date. (Torrent Br., at 5.) However, the record demonstrates that the contamination was evident long before August 3, 2018. (*See, e.g.,* SOMF ¶¶ 50, 50(a), 50(b).)

intentionally, and falsely represent that its product was FDA approved, valsartan USP. [REDACTED]

Despite Torrent's undeniable (and admitted) knowledge that the valsartan API was contaminated with nitrosamines, Torrent continued to represent that those drugs not only were "valsartan," [REDACTED]

[REDACTED] This conduct is fraudulent as a matter of law and Torrent's failure to address this period of time warrants denial of its Motion and granting Plaintiffs' motion for partial summary judgment.

2. Torrent Acted Intentionally

Intent is an element of fraud in only five of the twenty-three Subclass C states. While Torrent insists there is no evidence of intent, (Torrent's Br., at 5.), direct evidence of intent is not required. *See, e.g., Latta v. Rainey*, 689 S.E.2d 898, 909 (N.C. App. 2010). Instead, intent can be shown "by presenting evidence of some motive on the part of the perpetrator," *id.*, or "from circumstances which create a reasonable assumption that [it] recognized the materiality of the misrepresentations." *Fiveash v. Pat O'Brien's Bar, Inc.*, 201 So.3d 912, 919 (La. App. 2016) (quotations and emphasis omitted).⁶

⁶ *See also Chedick v. Nash*, 151 F.3d 1077, 1083 (D.C. App. 1998); *Rosen v. Bd. of Med. Examiners of State of Iowa*, 539 N.W.2d 345, 350 (Iowa 1995) (applying the common law fraud standard,); *First Nat'l Bank of Beresford v. Anderson* 291 N.W.2d 444, 446 (S.D. 1980); *Flip Motrg. Corp.*

Here, the undisputed material facts demonstrate that Torrent intended to make material misrepresentations and/or omissions to Plaintiffs, its customers, and the public. Specifically, Torrent's motive is clear, *see Latta*, 689 S.E.2d at 909. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] In short, the longer Torrent could delay a recall, the less money it would lose. *See id.* In addition, Torrent's recognition of the materiality of the misrepresentations cannot seriously be disputed. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Despite knowing [REDACTED]
[REDACTED] that Torrent's own valsartan contained this impurity (at least as of August 3, 2018), Torrent affirmatively misrepresented that its product was not contaminated or subject to a recall up to the very date a recall was issued. [REDACTED] The undisputed material

v. McElhone, 841 F.2d 531, 547 (4th Cir. 1988) (citing *Cook v. Hayden*, 31 S.E.2d 625, 627 (Va. 1944)).

facts are sufficient to establish intent and, on this basis, Torrent's Motion for Summary Judgment must be denied.

II. Plaintiffs are Entitled to Punitive Damages Against Torrent

Torrent's sole challenge to Plaintiffs' fraud-based punitive damages claim is that Plaintiffs failed to establish scienter. (Torrent Br., at 6–7.) As described above, the scienter element of Plaintiffs' fraud claim against Torrent is satisfied because Torrent made misrepresentations knowingly and with intent before and after August 3, 2018. In claiming that there is “no evidence” of scienter, Torrent wholly disregards its actual knowledge of nitrosamine contamination after August 3, 2018 and

Further, it ignores that even before August 3, 2018, the risk of nitrosamine contamination was evident from the route of synthesis.

Torrent's challenge to Plaintiffs' punitive damages claim, premised entirely on the absence of scienter, therefore collapses.

III. Torrent's VCDs Were Adulterated as a Matter of Law

The undisputed material facts establish that Torrent's VCDs were adulterated within the meaning of the FDCA as a matter of law. *See* 21 U.S.C.A. § 351(a)–(d); [ECF 2581 at 2 (“Beginning in July 2018 and upon the FDA's discovery that VCDs sold in the U.S. *were contaminated* with these nitrosamines...”)] (emphasis added). To be clear, Plaintiffs are not seeking to enforce the FDCA and this Court has ruled

as much. [See ECF 675.] Torrent nonetheless seeks to relitigate this Court’s prior rulings on preemption and primary jurisdiction, claiming that “only the FDA can make a determination that Torrent’s VCDs were adulterated,” and, counterfactually, that no such determination was made. (Torrent Br., at 8.).

The preemption and primary jurisdiction cases Torrent cites for the proposition that “only the FDA can make a determination that Torrent’s VCDs were adulterated,” (*see* Torrent’s Br., at 8) are inapposite.⁷ Plaintiffs are not seeking to enforce the FDCA; rather, their claims are premised on Torrent’s misrepresentations that its product was therapeutically equivalent to the branded valsartan in the Orange Book, when, in fact, it was adulterated with nitrosamines and therefore not saleable. The Court already ruled that Plaintiffs’ warranty, fraud, and consumer protection claims based on adulteration are *not* preempted or within the primary jurisdiction of the FDA. [ECF 675]. Torrent’s VCDs were adulterated within the meaning of the FDCA, 21 U.S.C.A. § 351(a)–(d), because they did not satisfy the quality and purity standards of the referenced listed drug in that they contained NDMA and NDEA, impurities not permitted in the valsartan monograph. (Torrent SOMF ¶ 24, 24(a),

⁷ *See Allergan, Inc. v. Athena Cosms., Inc.*, 738 F.3d 1350, 1359 (Fed. Cir. 2013) (enforcement of FDCA); *Healthpoint, Ltd. v. Stratus Pharmaceuticals, Inc.*, 273 F. Supp. 2d 769, 780–81 (W.D. Tex. 2001) (primary jurisdiction); *Agee v. Alphatec Spine, Inc.*, No. 1:15-CV-750, 2017 WL 5706002, at *3–5 (S.D. Ohio Mar. 27, 2017) (implied preemption).

24(b), 37.) This definition is satisfied irrespective of whether the FDA made a formal determination of the same.

There is no support in the record for the claim that the FDA “never found” that Torrent’s VCDs are adulterated. (*See* Torrent Br., at 8 (citing SUMF ¶ 101 (in turn citing Nagaich Rep. ¶ 85–87, 90).) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This was followed by a formal recall. The Court already affirmatively found that the “recall serves to point out that the VCDs at issue contained contaminants not listed in the Orange Book.” [ECF 675].

CONCLUSION

For the foregoing reasons, Defendants’ Motion for Summary Judgment should be denied.

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